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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,032	06/20/2003	David J. Hammond	70065.0003USU1	5177

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EXAMINER	
STEELE, AMBER D	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,032	HAMMOND ET AL.	
	Examiner	Art Unit	
	Amber D. Steele	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 4, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *7-10,13,16,17 and 25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 11-12, 14-15, and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-27 are pending.

Claims 1-6, 11-12, 14-15, and 18-24 are currently under consideration.

Election/Restrictions

2. This application contains claims 25-27 drawn to an invention nonelected with traverse in the reply received on May 10, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The species election is reiterated: peptide - species of ligand, polymethacrylate - species of support, conditioned cell medium - species of mixture/composition, protein - species of entity, and cell proliferation - species of activity.

New Rejection necessitated by Amendment

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The entity being assayed in step iv is indefinite. For example, is the assayed entity part of the entity-ligand-support complex (e.g. assay performed on the complex), is the entity the

unbound entity (e.g. assay performed on the unbound entity of method step iii), or is the entity a ligand specific entity which is no longer part of the entity-ligand-support complex?

Therefore, one of skill in the art would not be able to determine the scope of the presently claimed invention.

Maintained Rejections

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

7. Claims 1-6, 11-12, 14-15, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Todara U.S. Patent 4,816,561 issued March 28, 1989.

For present claims 1 and 18, Todara teaches a method of screening aqueous solutions for polypeptides (e.g. active entities) via providing antibodies or antigens attached to supports (e.g. ligand-support), contacting the antibodies or antigens on the supports with cells expressing TGF polypeptide (e.g. entity-ligand-support), separating the cells with a fluorescence activated cell sorter, assaying for cell growth, detecting cell growth, and selecting the molecule with activity **or** via HPLC columns (e.g. ligands-supports wherein ligands are for example hydrophobic alkyl chains), contacting aqueous heterogenous solutions with peptides of TGF (e.g. mixture with plurality of entities), separation, assaying for cell growth, detecting cell growth, and selecting TGF or TGF peptides (please refer to abstract; columns 5 and 10-16; Examples I-XV; Tables I-IX).

For present claim 2, Todara teaches that the ligands can be proteins, peptides, synthetic organic compounds (e.g. HPLC columns with hydrophobic alkyl chains; please refer to columns 4-6 and 14).

For present claim 3, Todara teaches that peptides can be generated by synthetic techniques, hybrid DNA technology techniques (e.g. combinatorial approaches; please refer to column 10).

For present claim 4, Todara teaches that the support can be an HPLC column (e.g. with silica/silicon), a solid support (e.g. beads = silicon; plates = polystyrene, etc.), polystyrene resin supports, or agar/agarose (please refer to columns 10, 12-14; Examples I-II).

For present claims 5-6, Todara teaches that a heterogenous aqueous solution including serum-free medium conditioned by various cells, urine, serum, plasma, whole blood, or cerebrospinal fluid can be utilized in the methods (please refer to columns 5 and 10-11; Examples I-II, XI).

For present claim 11, Todara teaches that the desired products in the solutions (see above for claims 5-6) can be polypeptides (e.g. proteins) or peptides (please refer to columns 6-10).

For present claims 12 and 14-15, Todara teaches that the polypeptides or peptides can be screened for activities including cell proliferation and EGF binding (please refer to columns 11-12; Examples I-II).

For present claim 20, Todara teaches chemical synthesis and characterization of peptides (e.g. chemical identity; please refer to Examples V, XI, and XV).

Therefore, the presently claimed invention is anticipated by the teachings of Todara.

Arguments and Response

8. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Todara for claims 1-6, 11-12, 14-15, 18, and 20 were considered but are not persuasive for the following reasons.

Applicants contend that Todora does not teach "separating at least one entity-ligand-support complex from the unbound entities, and, assaying the activity of the entity of the at least one entity-ligand-support complex separated in step (iii) as is claimed in newly amended claim 1".

Applicants' arguments are not convincing since the teachings of Todora anticipate the method of screening of the instant claims. Todora teaches "a process for isolating homogenous transforming growth factor polypeptides from less pure aqueous solutions...including body fluids and aqueous medium"; elution of TGF from columns and assaying the TGF for activity; solid supports with either antigen or antibody bound wherein a solid support with an antibody can be utilized to capture antigens in a physiological fluid, on a cell, or in cell lysates and the antigen (e.g. TGF) can be isolated from a heterogenous cell population via FACS; the TGF can then be further purified and assayed for activity (e.g. separation from unbound entities; please refer to column 5, lines 44-67; column 6, lines 1-25; column 12, lines 1-34; column 14, lines 41-63; column 15, lines 24-37; Examples I-IV, IX-XII). Thus, Todora teaches each and every limitation of the presently claimed method.

9. Claims 1-6, 11-12, 14-15, and 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al. U.S. Patent 5,510,240 issued April 23, 1996.

For present claims 1 and 18, Lam et al. teach methods of screening peptide libraries via library of bio-oligomers (e.g. peptides) attached to solid phase supports (e.g. ligand-support), introducing an acceptor molecules or substrate molecule (e.g. protein) that recognizes and binds the solid phase support-bio-oligomer (e.g. entity-ligand-support), washing nonbound molecules from the mixture, assaying for binding or chemical reaction, detecting binding or the chemical reaction, and isolating a support/bio-oligomer/molecule with the desired property including binding, stimulation, inhibition, toxicity, etc. (e.g. activity) (please refer to abstract; sections 1, 3, 5.1, 5.4, 5.5 including 5.5.1-5.5.3; Example sections 6-14; Figures 1-2 and 4-8D).

For present claims 2-3, Lam et al. teach that the ligands can be peptides or nucleic acids (please refer to sections 5.1, 5.2, 5.3).

For present claim 4, Lam et al. teach that the supports can be silica, resin, plastic films, glass beads, alumina gels, polystyrene, polydimethylacrylamide (e.g. polymethacrylate; please refer to section 5.4).

For present claims 5-6, Lam et al. teach that the cells and conditioned culture medium can be utilized in the screening methods (please refer to sections 5.5.2.1).

For present claim 11, Lam et al. teach that the molecule (e.g. entity) can be protein, antibody, enzyme, cell, receptor, virus, carbohydrate, drugs, lipids (please refer to sections 5.5, 5.5.1).

For present claims 12 and 14-15, Lam et al. teach determining activities including binding, stimulation, inhibition, toxicity, enzyme activity, killing, growth promotion, physiological change (please refer to sections 5.5 including 5.5.1, 5.5.2).

For present claim 19, Lam et al. teach that the beads can be partitioned and separated into smaller pools (e.g. subpools; please refer to sections 5.5.1, 5.5.2).

For present claims 20 and 23, Lam et al. teach identifying peptide sequences including sequencing (please refer to section 5.5.2; Tables 1-5; Examples 10-13).

For present claims 21 and 22, Lam et al. teach that the screening assay can repeated several times and that cleavable linkers can be utilized to recover the peptides bound to the supports (sections 5.1, 5.5.1, 5.5.2, 5.4).

For present claim 24, Lam et al. teach that cleavage and/or release of the components of the molecule-peptide-support is possible (please refer to 5.1, 5.5.1, 5.5.2, 5.4).

Therefore, the presently claimed invention is anticipated by the teachings of Lam et al.

Arguments and Response

10. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Lam et al. for claims 1-6, 11-12, 14-15, and 18-24 were considered but are not persuasive for the following reasons.

Applicants contend that Lam et al. does not teach "separating at least one entity-ligand-support complex from the unbound entities, and, assaying the activity of the entity of the at least one entity-ligand-support complex separated in step (iii) as is claimed in newly amended claim 1". In addition, applicants contend that Lam et al. teaches separating a single-phase support/bio-oligomer combination from other bio-oligomer solid phase supports and not separating from unbound entities.

Applicants' arguments are not convincing since the teachings of Lam et al. anticipate the method of screening of the instant claims. Lam et al. teaches solid phase supports with bio-

oligomers that bind various acceptor molecules or substrate molecules wherein the acceptors/substrates include biological macromolecules, antibodies, receptors, viruses, chemical compounds, proteins, carbohydrates, nucleic acids, lipids, drugs, metals, small molecules, cells, cell-surface receptors and assaying for activities (please refer to column 4, lines 65-67; column 5, lines 1-45; column 17, lines 26-39; column 19, lines 10-41; section 5.5.2). In addition, Lam et al. teaches panning with both non-biooligomer specific proteins/cells and biooligomer specific proteins/cells (please refer to column 19, lines 23-41). Furthermore, while Lam et al. does teach separating support-biooligomer-acceptor/substrates from support-biooligomers, both the unbound support-biooligomers and unbound acceptors/substrates are separated from the support-biooligomer-acceptor/substrates. Thus, Lam et al. teaches each and every limitation of the presently claimed method.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS
February 23, 2007

MARK L. SHIBUYA
PRIMARY EXAMINER